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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,565	11/14/2006	Kei Mizuno	5426SI-2	6198
22442	7590	08/19/2009	EXAMINER	
SHERIDAN ROSS PC			GOUGH, TIFFANY MAUREEN	
1560 BROADWAY				
SUITE 1200			ART UNIT	PAPER NUMBER
DENVER, CO 80202			1657	
			MAIL DATE	DELIVERY MODE
			08/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/581,565	MIZUNO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	TIFFANY M. GOUGH	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 20 May 2009.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-19 is/are pending in the application.  
 4a) Of the above claim(s) 1-7 and 16-19 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 8-15 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>6/2/2006</u> .	6) <input type="checkbox"/> Other: _____ .

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election without traverse of claims 8-15 in the reply filed on 5/20/2009 is acknowledged.

Claims 1-7, 16-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claims 8-15 have been examined on the merits herein.

***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for evaluating a degree of fatigue in a human, does not reasonably provide enablement for evaluating a degree of fatigue in any “organism”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. An organism is defined as any living system such as an animal, plant, fungus or microorganism including unicellular and multicellular

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organisms. Not all organisms have body fluid from which amino acid concentrations can be measured and used in the instant invention, nor would all organisms be capable of experiencing fatigue, in particular mental fatigue. The sole examples provided in the disclosure teach measuring amino acids from bodily fluids of a human and in addition measuring before and after fatigue loading. Given the differences among "organisms", one of ordinary skill in the art would not expect to be able to practice the invention with any organism encompassed by the current claim language. Thus, with the exception of the humans, and in view of the lack of any specific guidance with respect to how one would practice the invention with any organism, other than what is encompassed by the claims, one skilled in the art would expect a trial and error process to determine organism encompassed by the claims would apply to the as disclosed application, and would further have to determine through undue experimentation, without guidance from the specification, how to perform such a method.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary, limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 and dependent claims 9-15 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how fatigue is determined from using the index indicative of a concentration of amino acids in a body fluid of the organism. At present, the claim merely requires using an index, but there is no step indicating what one does with the index and how one would use the index to evaluate the degree of fatigue.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "substantially" in claim 13 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8, 11, 12, 13, 14, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by McGuire et al. (BRB, 2003, p. 125-130).

Applicant claims a fatigue evaluation method for evaluating a degree of fatigue in an organism comprising using an index indicative of a concentration of amino acid in a body fluid such as blood , saliva, cerebrospinal fluid, and urine from the organism. The fatigue is evaluated by using a change in concentration of amino acid as an index before and after fatigue loading. Applicants also claim the method to further include providing a kit for carrying out the method.

McGuire teach a fatigue evaluation method for evaluating a degree of fatigue in an organism comprising using an index indicative of a concentration of amino acid in a body fluid from the organism. McGuire teach measuring a change in tryptophan and branched chain amino acids before and after surgery. Patients were evaluated for fatigue levels by evaluating blood samples and fatigue questionnaires (p. 126-130).

McGuire uses a “fatigue evaluation kit” to practice the disclosed method.

Thus, the reference anticipates the claimed invention.

Claims 8-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Lord et al. (Journal of Applied Nutrition, 1994).

Lord teach a fatigue evaluation method for evaluating a degree of fatigue in an organism comprising using an index indicative of a concentration of amino acid in a body fluid from the organism. Lord teach measuring in fatigue patients a change in amino acids before and after amino acid mixture treatments. Patients were evaluated by measuring amino acid levels of plasma which were reported to be below reference ranges (p. 1-5). Lord uses a “fatigue evaluation kit” to practice the disclosed method.

Thus, the reference anticipates the claimed invention.

Claims 8-12, 14, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kingsbury et al. (British Journal of Sports medicine, 1994).

Kingsbury teach a fatigue evaluation method for evaluating a degree of fatigue in an organism comprising using an index indicative of a concentration of amino acid in a body fluid from the organism. Kingsbury teach measuring in fatigue patients a change in amino acids before and after fatigue loading, i.e. Olympic training. Patients were evaluated by amino acid profiling (p.26-31 Tables 1-4, especially 1, Fig. 1,2) which were reported to be below reference levels. Kingsbury uses a “fatigue evaluation kit” to practice the disclosed method.

Thus, the reference anticipates the claimed invention.

Claims 8-15 are rejected under 35 U.S.C. 102(b) as being anticipated by JP11-304792 (cited on IDS).

JP'792 teach a fatigue evaluation method for evaluating a degree of fatigue in an organism comprising using an index indicative of a concentration of amino acid in a body fluid from the organism. JP'792 teach measuring a change in alanine levels in blood from animals before and after fatigue loading (0012-0022 of translated document). JP'792 uses a “fatigue evaluation kit” to practice the disclosed method.

Thus, the reference anticipates the claimed invention.

Claims 8,11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by JP11-304793 (cited on IDS).

JP'793 teach a fatigue evaluation method for evaluating a degree of mental fatigue in an organism comprising using an index indicative of a concentration of amino acid in a body fluid from the organism. JP'793 teach measuring a change amino acid levels in blood from animals before and after fatigue loading (0012-0022 of translated document). JP'793 uses a “fatigue evaluation kit” to practice the disclosed method.

Thus, the reference anticipates the claimed invention.

Claims 8, 11, 12, 14, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Struder et al. (Eur. J. Applied Physiology, 1999, cited on IDS).

Struder teach a fatigue evaluation method for evaluating a degree of fatigue in an organism comprising using an index indicative of a concentration of amino acid in a body fluid from the organism. Struder teach measuring fatigue in patients by measuring a change in amino acids before and after fatigue loading, i.e. exercise. Patients were evaluated by measuring changes in tryptophan and BCAA (p.319-322, Methods section, Table 2, Results section). Struder uses a “fatigue evaluation kit” to practice the disclosed method.

Thus, the reference anticipates the claimed invention.

Claims 8-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Blomstrand, Amino Acids 2001, p.25-34).

Blomstrand teaches a fatigue evaluation method for evaluating a degree of mental fatigue in an organism comprising using an index indicative of a concentration of amino acid in a body fluid from the organism. Blomstrand teaches measuring a change amino acid levels in blood from humans before and after fatigue loading. Blomstrand teaches a decrease in branched chain amino acids (BCAA) during and after exercise and also reports of mental fatigue after such physical conditions (p.27-30, table 1, Fig. 1). Blomstrand uses a “fatigue evaluation kit” to practice the disclosed method.

Thus, the reference anticipates the claimed invention.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY M. GOUGH whose telephone number is (571)272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/  
Primary Examiner, Art Unit 1657

/Tiffany M Gough/  
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